

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**

k031545

**B. Analyte:**

ESBL detection and confirmation

**C. Type of Test:**

Qualitative broth based growth detection using Ceftazidime/clavulanic acid at 0.06/4-128/4 ug/ml and Cefotaxime/clavulanic acid at 0.06/4-64/4 ug/ml

**D. Applicant:**

Trek diagnostics Systems

**E. Proprietary and Established Names:**

Sensititre® 18-24 hour Susceptibility plate

**F. Regulatory Information:**

1. Regulation section:  
CFR 866.1640 Antimicrobial Susceptibility Test
2. Classification:  
II
3. Product Code:  
JWY
4. Panel:  
83

**G. Intended Use:**

1. Indication(s) for use:  
The Sensititre ESBL confirmatory test plate is an *in vitro* diagnostic product for detection of ESBL's in clinical isolates of *Klebsiella pneumoniae*, *Klebsiella oxytoca* and *Escherichia coli*. Test results can be read either manually or automatically on a Sensititre® ARIS or Autoreader.
2. Special condition for use statement(s):
3. Special instrument Requirements:

**H. Device Description:**

The 96 well panel contains precision dosed antimicrobial agents that are dried.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):  
Dade MicroScan
2. Predicate K number(s):  
K020037
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
specimen	Suspect colonies of E. coli, K. pneumonia or K oxytoca	Suspect colonies of E. coli, K. pneumonia or K oxytoca
Incubation	>15 hours	>15 hours
panels	Dried antimicrobial agents	Dried antimicrobial agents
Differences		
Item	Device	Predicate
Antibiotic concentrations	Ceftazidime/clavulanic acid at 0.06/4-128/4 ug/ml Cefotaxime/clavulanic acid 0.06/4-64/4 ug/ml	Ceftazidime/clavulanic acid at 0.12/4-32/4 ug/ml Cefotaxime/clavulanic acid 0.12/4-32/4 ug/ml

**J. Standard/Guidance Document Referenced (if applicable):**

NCCLS standard reference method from M7 A6.

**K. Test Principle:**

Results are based on broth based turbidity detection of growth in wells containing antimicrobial agents. The wells also contain a fluorescence which is used in the auto reading with the instrumentation where fluorescence indicates the presence of microbial growth.  $A \geq 3$  twofold concentration decrease in an MIC for either Ceftazidime or Cefotaxime tested in combination with clavulanic acid versus its MIC when tested alone would define the organism as an ESBL producer.

**L. Performance Characteristics (if/when applicable):**1. Analytical performance:a. *Precision/Reproducibility:*

Reproducibility was determined to be >95% when the individual antibiotics were cleared for use on the gram negative Sensititre® panels.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability (controls, calibrators, or method):*

Quality control was performed on the NCCLS recommended organisms with acceptable results using both the manual and the Autoread methods. Each of the four sites tested the confirmatory test 20 times resulting in only one failure.

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable

f. *Assay cut-off:*

Not applicable

2. Comparison studies:a. *Method comparison with predicate device:*

NCCLS reference method used for comparison along with molecular characterization methods

b. *Matrix comparison:*

Not applicable

3. Clinical studies:

a. *Clinical sensitivity:*

b. *Clinical specificity:*

c. *Other clinical supportive data (when a and b are not applicable):*

A study was performed at three sites on 513 isolates of *Klebsiella pneumoniae*, *Klebsiella oxytoca*, and *Escherichia coli* and compared to the reference method. Percent agreement to the reference method was established with the following results:

	Reference ESBL positive	Reference ESBL negative
Manual read of Sensititre panel	97.3% (392/403)	95.4% (105/110)
Autoread of Sensititre panel	98.3% (396/403)	96.4% (106/110)

An additional study was performed at one site on 30 molecular characterized isolates with a 100% agreement for both the manual method of reading and the fluorogenic autoread.

4. Clinical cut-off:

5. Expected values/Reference range:

A  $\geq 3$  twofold concentration decrease in an MIC for either Ceftazidime or Cefotaxime tested in combination with clavulanic acid versus its MIC when tested alone = ESBL.

**M. Conclusion:**

Acceptable performance was provided to demonstrate that the Sensititre 18-24 Susceptibility panel can detect and confirm the presence of ESBL producing *Klebsiella pneumoniae*, *Klebsiella oxytoca*, and *Escherichia coli* and is substantially equivalent to the predicate listed above.